DISTILLED SPIRITS COUNCIL
OF THE UNITED STATES

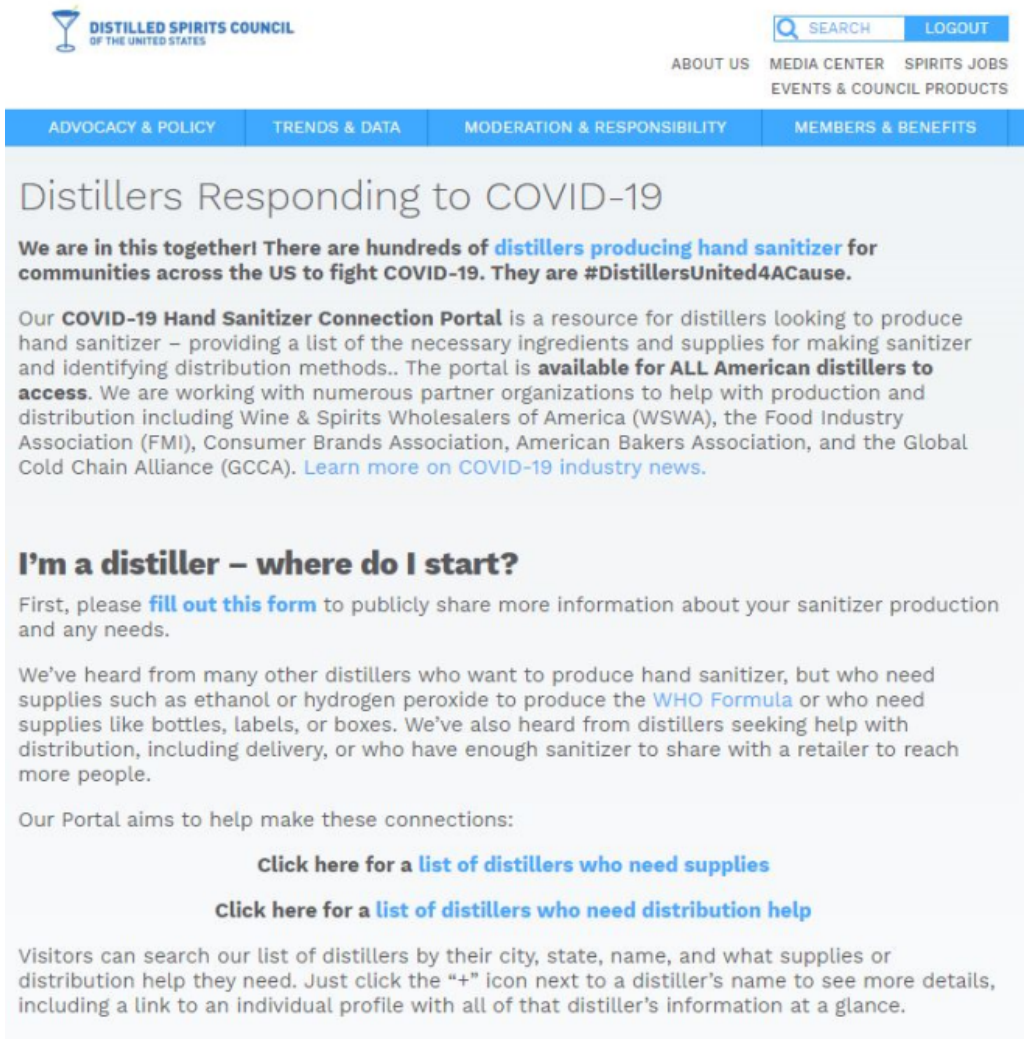
GRAY | ROBINSON
ATTORNEYS AT LAW

LENDING A HELPING HAND

What Distilleries Should Know In Order To Legally and Responsibly Produce Hand Sanitizer

WHERE THINGS STAND RIGHT NOW

- (A) DISCUS COVID-19 Portal: https://www.distilledspirits.org/distillers-responding-to-covid-19/
- (B) Confirmed positives: **164,785**
- (C) Reported deaths: **2,801**
- (D) Forecasted Need for Sanitizers (UPS anecdote; truckers and maintenance workers) **Hand Sanitizers market worldwide is projected to grow to US$2.14 Billion by 2027, driven by a compounded annual growth rate of 7.5%.** https://www.globenewswire.com/news-release/2020/03/26/2007160/0/en/Global-Hand-Sanitizer-Market-Is-Expected-to-Reach-USD-2-14-Billion-by-2027-Fior-Markets.html
- (E) List of distillers already participating in the sanitizer initiative https://www.distilledspirits.org/distillers-responding-to-covid-19/distilleries-producing-hand-sanitizer/



DISTILLED SPIRITS COUNCIL OF THE UNITED STATES

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ABOUT US MEDIA CENTER SPIRITS JOBS EVENTS & COUNCIL PRODUCTS

ADVOCACY & POLICY | TRENDS & DATA | MODERATION & RESPONSIBILITY | MEMBERS & BENEFITS

Distillers Responding to COVID-19

We are in this together! There are hundreds of distillers producing hand sanitizer for communities across the US to fight COVID-19. They are #DistillersUnited4ACause.

Our **COVID-19 Hand Sanitizer Connection Portal** is a resource for distillers looking to produce hand sanitizer – providing a list of the necessary ingredients and supplies for making sanitizer and identifying distribution methods.. The portal is **available for ALL American distillers to access**. We are working with numerous partner organizations to help with production and distribution including Wine & Spirits Wholesalers of America (WSWA), the Food Industry Association (FMI), Consumer Brands Association, American Bakers Association, and the Global Cold Chain Alliance (GCCA). Learn more on COVID-19 industry news.

I'm a distiller – where do I start?

First, please **fill out this form** to publicly share more information about your sanitizer production and any needs.

We've heard from many other distillers who want to produce hand sanitizer, but who need supplies such as ethanol or hydrogen peroxide to produce the WHO Formula or who need supplies like bottles, labels, or boxes. We've also heard from distillers seeking help with distribution, including delivery, or who have enough sanitizer to share with a retailer to reach more people.

Our Portal aims to help make these connections:

Click here for a list of distillers who need supplies

Click here for a list of distillers who need distribution help

Visitors can search our list of distillers by their city, state, name, and what supplies or distribution help they need. Just click the "+" icon next to a distiller's name to see more details, including a link to an individual profile with all of that distiller's information at a glance.

The CARES Act and What It Provides

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law on March 27, 2020. The 854-page bill provides approximately $2 trillion in relief and assistance to individuals, businesses, state governments, health providers and others affected by the COVID-19 outbreak.

The following summary highlights the programs, initiatives, and relief measures created or expanded by the new law for small businesses:

Relief for Small Businesses (1 - 500 employees)

- **The CARES Act** seeks to make it possible for small businesses not only to survive the COVID-19 outbreak, but also to keep their employees paid and insured for at least the next eight weeks. The Small Business Administration will be responsible for most of these programs, but private lenders will be actively involved.
- **SBA 7(a) program expansion**. The SBA's 7(a) loan program has been expanded to include a new Paycheck Protection Program that makes loans available to any business, 501(c)(3) nonprofit organization, veterans group or tribal business with 500 employees or fewer; to sole proprietors, independent contractors, and other self-employed workers; and to hotel and food service chains with 500 or fewer employees per location. The 7(a) loan program limit has been raised to $10 million or 250% of average monthly total payroll costs, with interest rates capped at 4%, and payments deferred for at least six months, up to one year. Borrowers under this Paycheck Protection Program can apply for loan forgiveness for up to eight weeks of payroll costs, mortgage interest, rent, and utility payments, with the SBA paying lenders for accrued debt plus interest.
- **Economic Injury Disaster Loan (EIDL) program expansion**. The SBA's Economic Injury Disaster Loan program has received an additional $10 billion from January 31 through Dec. 31 to cover businesses, cooperatives, employee stock ownership plans, and tribal businesses with 500 or fewer employees, as well as sole proprietors and independent contractors. The SBA may advance as much as $10,000 to existing and newly eligible EIDL recipients within three days of receiving their applications. Recipients can use the advance funds to pay sick leave to employees affected by COVID-19, retain employees, address interrupted supply chains, make rent or mortgage payments, and repay debt. Recipients are not required to repay the advance funds, even if their loan application is ultimately denied.

The CARES Act and What It Provides

- **Payroll tax deferral**. Employers may defer their payroll taxes through December 31, 2020, and pay those deferred taxes over a two-year period ending in December 2022. Employers with small business loan debt forgiven under the Paycheck Protection Plan are not eligible for this deferral. Self-employed taxpayers may defer 50% of their Social Security tax payments.
- **Employee retention credit**. Certain employers may receive refundable credits of up to 50% of eligible employee wages paid between March 12, 2020 and January 1, 2021. Employers can qualify for this credit if they must partially or fully suspend operations because of a pandemic-related government order, or if their income drops below a certain threshold. Employers with more than 100 full-time employees in 2019 will receive credit for wages paid to employees who aren't working; employers of fewer than 100 people will receive credit for wages paid while operations are suspended, or during a quarter when the company suffers a significant decline in gross receipts. Employers who receive loans under the Paycheck Protection Plan will not receive these credits, and employers may not apply for credit on wages they receive credit for under the work opportunity tax credit or the paid leave credit.
- **Business losses**. Companies may carry back business losses from tax years between December 31, 2017 and January 1, 2021 for five years (separate rules apply for REITs and life insurance companies). Companies may use the full amount of net operating loss carryovers and carrybacks for tax years up to January 1, 2021, an increase from the 80% limit set in 2017. Net operating loss deduction limits will change for pass-through businesses and sole proprietorships as well.
- **Charitable contributions**. The limit for corporate charitable deductions has been raised from 10% to 25% for 2020. The deduction for food inventory contributions has been raised from 15% to 25% for 2020.
- **Interest expenses**. Businesses may deduct 50% of their interest expenses in 2019 and 2020, instead of 30%.

The CARES Act and What It Provides

- **A fix for the "retail glitch**." The CARES Act fixes the so-called "retail glitch" in the 2017 tax bill, which extended the depreciation schedule for qualified improvements by certain restaurants and retail businesses to 39 years. Qualified improvement properties will be classified as 15-year property, or as 20-year property under an alternative depreciation system, which would make the property eligible for temporary "bonus depreciation" under the 2017 law.
- **Alcohol excise tax changes. Hand sanitizer produced and distributed in 2020 in response to the pandemic and pursuant to FDA regulations will be exempt from the federal excise tax on distilled spirits. Hand sanitizer produced under these conditions also will be exempt from federal bulk sales and labeling requirements.**
- **Leave program modifications**. The CARES Act modifies the emergency sick leave program created by the Families First Coronavirus Response Act. Under the new law, certain workers laid off on or after March 1, 2020, are eligible for family leave benefits if they're rehired. Federal agencies may use funds to reimburse federal contractors for providing paid pandemic-related leave to employees or subcontractors through September 30, 2020.
- **Bankruptcy code changes**. The Act raises the limit for streamlined Chapter 11 for small businesses from $2.73 in debts to $7.5 million. It also excludes federal payments related to COVID-19 from income calculations in Chapter 11, and allows those companies in Chapter 11 to modify their existing reorganization plans if they are experiencing COVID-19 hardships.

For more specific details, go online to: http://www.gray-robinson.com/blog/post/2472/grayrobinson-covid-19-task-force-e-lert-the-coronavirus-aid-relief-and-economic-security-cares-act-summary

Clarifying Guidance and Removing Roadblocks

LATEST TTB POSITION (3/27/2020):

TTB revised its public guidance on "Production of Hand Sanitizer to Address the COVID-19 Pandemic" to reflect changes in FDA policy and to allow for additional flexibility. This guidance now acknowledges that FDA requires hand sanitizer products to be manufactured with denatured alcohol and points DSPs to FDA's allowable denaturing formulas.

TTB now formally exempts DSPs from the requirements to request approval to receive **denatured** distilled spirits in-bond from another DSP.

TTB's new guidance also provides some helpful clarity to further exempt some undenatured alcohol used to produce hand sanitizer:

- It provides certain exemptions for alcohol, whether or not denatured, to be delivered tax-free to state and local governments for non-beverage purposes.
- Additionally, it provides that the FET will not apply to undenatured alcohol provided for use by hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale.

TTB COVID-19 GUIDANCE

- Tax-free ethanol may be used by DSPs and AFPs to produce hand sanitizer if it is denatured according to TTB regulations and FDA guidance. **Alcohol MUST be denatured**.
- Alcohol, **whether or not denatured**, may be delivered tax-free to state and local governments for non-beverage purposes. The same is true for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions, if not for resale or use in the manufacture of any product for sale.
- **TTB is temporarily waiving certain formula approvals for the manufacture of hand sanitizer and expediting certain permit requirements**.
- Distilled spirits permittees who wish to produce ethanol-based hand sanitizers to address the demand for such products during the COVID-19 emergency can immediately commence production of hand sanitizer or distilled spirits (ethanol) for use in hand sanitizer, without having to first obtain authorization. USE AN EXISTING APPROVED FORMULA, OR A WORLD HEALTH ORGANIZATION (WHO) FORMULA CONSISTENT WITH FDA GUIDANCE.
- Any existing DSP also may remove undenatured or denatured ethanol from bonded premises free of tax for use by any state or local government to produce hand sanitizer.
- In addition, any existing DSP may remove undenatured or denatured ethanol from bonded premises free of tax for use by hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions seeking to use it to manufacture hand sanitizer, and not for resale or use in the manufacture of any product for sale.

TTB COVID-19 GUIDANCE

Permit guidance for alcohol fuel plants (AFPs) and beverage DSPs:

- TTB is exempting AFPs and beverage DSPs from the requirement to obtain additional permits or bonds to manufacture hand sanitizer or to supply ethanol for use in the manufacture of hand sanitizer to other TTB permittees who are authorized to receive such distilled spirits.
- Beverage DSPs must continue to keep records of their operations, including any undertaken as authorized under this exemption.

TTB COVID-19 GUIDANCE

***Tax guidance for the manufacture of hand sanitizer*:**

Nonbeverage products made with ethanol, including hand sanitizer, are not subject to federal excise tax, **SO LONG AS** the manufacturer complies the FDA guidance regarding the use of denaturants when compounding hand sanitizer.

***Formula guidance for the manufacture of hand sanitizer*:**

TTB is authorizing the manufacture of hand sanitizer products by DSPs using a WHO formulation consistent with the FDA's COVID-19 guidance, without first obtaining formula approval from TTB.

TTB COVID-19 GUIDANCE

Guidance for industrial alcohol users:

TTB is also exempting industrial alcohol user permittees from the requirement to request approval from TTB to increase the quantities of denatured ethanol that they may procure.

Guidance regarding transfers in bond.

Under current TTB regulations, when DSPs want to receive either denatured or undenatured ethanol from another domestic DSP, the receiving DSP must submit an application to TTB for authorization prior to the first transfer and ensure appropriate bond coverage. During the period covered by TTB'S COVID-19 guidance, for transfers of either denatured or undenatured distilled spirits between domestic DSPs, TTB is exempting DSPs from the requirements to request approval from TTB to receive denatured or undenatured distilled spirits from another DSP and to obtain additional bond coverage.

Rather than submit such requests to TTB for approval using TTB F 5100.16, **DSPs must maintain records of such receipts**, which would include records of the information currently required on TTB F 5100.16.

TTB COVID-19 GUIDANCE

Guidance for state and local governments:

Consistent with 27 CFR Part 22, both denatured **and** undenatured alcohol **may be removed free of tax** for the use of a **state, any political subdivision of a state, or the District of Columbia,** for nonbeverage purposes, including making hand sanitizer.

- An alcohol user permit is required to obtain alcohol from a distilled spirts plant. TTB provides state and local governments with a streamlined application. TTB has dedicated personnel to process such applications seven days a week given the COVID-19 emergency. Please note that the EMERGENCY FDA guidance cited above specifies using denaturants when compounding hand sanitizer.
- During the period of its COVID-19 guidance, TTB is authorizing state and local government permittees to make hand sanitizer for use anywhere, as needed to address the COVID-19 national emergency.

TTB COVID-19 GUIDANCE

***Guidance for hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions*:**

Consistent with 27 CFR Part 22, **hospitals, blood banks, sanitariums, certain pathological laboratories, non-profit clinics, and qualifying educational institutions may obtain alcohol free of tax for their own nonbeverage purpose use** and not for resale or use in the manufacture of any product for sale. Manufacturing hand sanitizer is one such nonbeverage use.

- As with state and local governments, such alcohol must be obtained from a distilled spirits plant and may only be obtained by those holding an alcohol user permit from TTB.
- TTB will offer these organizations the same streamlined application, as authorized for state governments. Again, please note that recent EMERGENCY FDA guidance specifies using denaturants when making hand sanitizer.

SOURCING DISTILLING MATERIALS FROM A BREWERY

Statute 26 U.S. Code §5053(f) REMOVAL FOR USE AS DISTILLING MATERIAL: Beer may be removed from a brewery without payment of tax to any distilled spirits plant for use as distilling material.

26 U.S. Code §5412 Removal of beer in containers or by pipeline: Beer may be removed from the brewery for consumption or sale only in hogsheads, packages, and similar containers, marked, branded, or labeled in such manner as the Secretary may by regulation require, except that beer may be removed from the brewery pursuant to section 5414 or by pipeline to contiguous distilled spirits plants under section 5222.

Regulation 27 CFR Part §25.201 Removal by pipeline: A brewer may remove beer from the brewery, without payment of tax, by pipeline to the bonded premises of a distilled spirits plant which is authorized to produce distilled spirits and which is located contiguous to the brewery.

§25.292 Daily records of operations. (a) *Daily records.* A brewer shall maintain daily records of operations which show by quantity the following:

(9) Beer removed without payment of tax. For each removal, the record will show the date of removal, the person to whom the beer was shipped or delivered, and the quantities of beer removed in kegs, bottles, tanks, tank cars, tank trucks, tank ships, barges or deep tanks of vessels.

Statute - 26 U.S. Code § 362 Removals of wine from bonded wine cellars

(c)WITHDRAWALS OF WINE FREE OF TAX OR WITHOUT PAYMENT OF TAX Wine on which the tax has not been paid or determined may, under such regulations and bonds as the Secretary may deem necessary to protect the revenue, be withdrawn from bonded wine cellars—
(6) without payment of tax for use in distillation in any distilled spirits plant authorized to produce distilled spirits;

SOURCING DISTILLING MATERIALS FROM A WINERY

Statute - 26 U.S. Code §5362 Removals of wine from bonded wine cellars:

(c)WITHDRAWALS OF WINE FREE OF TAX OR WITHOUT PAYMENT OF TAX Wine on which the tax has not been paid or determined may, under such regulations and bonds as the Secretary may deem necessary to protect the revenue, be withdrawn from bonded wine cellars— **(6)** without payment of tax for use in distillation in any distilled spirits plant authorized to produce distilled spirits;

Regulation – 27 CFR §24.216 Distilling material:
Wine may be produced on bonded wine premises from grapes and other fruit, natural fruit products, or fruit residues, for use as distilling material, using any quantity of water desired to facilitate fermentation or distillation. No sugar may be added in the production of distilling material. Distillates containing aldehydes may be used in the fermentation of wine to be used as distilling material. Lees, filter wash, and other wine residues may also be accumulated on bonded wine premises for use as distilling material.
§24.306 Distilling material or vinegar stock record
A proprietor who produces or receives wine containing excess water which will be used expressly as distilling material or vinegar stock shall maintain a record by transaction date showing the amount and kind produced, received, from whom received, removed, and to whom sent. The proprietor shall keep a record of each type of material from which the distilling material or vinegar stock was fermented (e.g., grape, apple, strawberry). The volume of distilling material or vinegar stock produced, including wine lees refermented for use as distilling material, will be recorded upon removal from fermenting tanks. However, the provisions of this section do not apply to standard wine or unwatered wine lees recorded on the proprietor's record of bulk still wine and bulk still hard cider and removed for use as distilling material or vinegar stock.

TTB COVID-19 GUIDANCE

TAKE NOTE: Although TTB is exempting industry members from certain tax requirements, **industry members must continue to comply with other federal and state law**, and industry members should contact relevant federal or state agencies with questions about guidance issued by those agencies.

DISTILLED SPIRITS COUNCIL OF THE UNITED STATES

FDA U.S. FOOD & DRUG ADMINISTRATION

GRAY ROBINSON RELATIONSHIPS | RESOURCES | RESULTS

Clarifying Guidance and Removing Roadblocks

As hospitals, nursing homes and others desperately search for antiviral sanitizers amid the COVID-19 outbreak, federal regulators are working with ethanol producers, including distillers who seek to switch production during this pandemic, to try and provide millions of additional gallons of alcohol that can be transformed into sanitizing products.

The challenge for the ethanol industry is that most plants make food-grade ethanol, one step below the highest pharmaceutical grade. But because the DSPs are not certified to comply with stringent production standards designed to protect quality of medicines, food ingredients and dietary supplements, the U.S. Food and Drug Administration typically has not approved the alcohol used for a product to be applied to the skin.

An additional challenge involves alcohol that is not denatured or mixed with a bitter additive to make it non-potable. **The FDA insists denaturing is "critical" because of cases of poisoning, sometimes fatal, among young children who have accidentally ingested hand sanitizers**. FDA reports that regulators already have seen a rise in poisonings linked to hand sanitizers in recent weeks, and that these incidents require "heightening this public concern."

To address these concerns, the FDA promulgated emergency guidance to secure assurances from the distilling industry that undenatured sanitizers could be distributed in a way that would keep them away from children. These assurances are key to securing the revised guidelines needed from FDA to allow distillers to proceed with confidence in the production of sanitizing agents using undenatured alcohol.

DISTILLED SPIRITS COUNCIL OF THE UNITED STATES

U.S. FOOD & DRUG ADMINISTRATION

GRAY ROBINSON RELATIONSHIPS | RESOURCES | RESULTS

Clarifying Guidance and Removing Roadblocks

The COVID-19 stimulus bill requires distillers to follow the FDA's guidance if they want to receive the waiver of FET tax on alcohol used to make sanitizing agents. Under the latest FDA guidelines, regulators maintain standards for alcohol, requiring producers of sanitizers to use alcohol that meets federal or international standards for use in pharmaceuticals.

The FDA has waived dozens of regulations in recent weeks to boost production of key medical supplies, including coronavirus tests, ventilators, gloves and hand sanitizers. **DISCUS is urging the FDA to update its guidance and let distillers use beverage-grade undenatured alcohol for hand sanitizer, but for now FDA continues to insist on the use of denatured alcohol only.**

The regulatory hurdles are especially frustrating for Midwest ethanol producers who are facing plunging fuel demand and a petroleum fight between Saudi Arabia and Russia that caused prices to plummet. The factors are forcing more plants to curtail production and close.

DISCUS continues to pursue this issue with FDA because for ethanol producers, as well as DSPs that want to shift from distilling spirits to producing sanitizers, relaxed rules -- including a requirement of the hard-to-acquire denaturant -- would allow them to step in an help in a national emergency.

DISTILLED SPIRITS COUNCIL OF THE UNITED STATES

U.S. FOOD & DRUG ADMINISTRATION

GRAY ROBINSON RELATIONSHIPS | RESOURCES | RESULTS

Clarifying Guidance and Removing Roadblocks

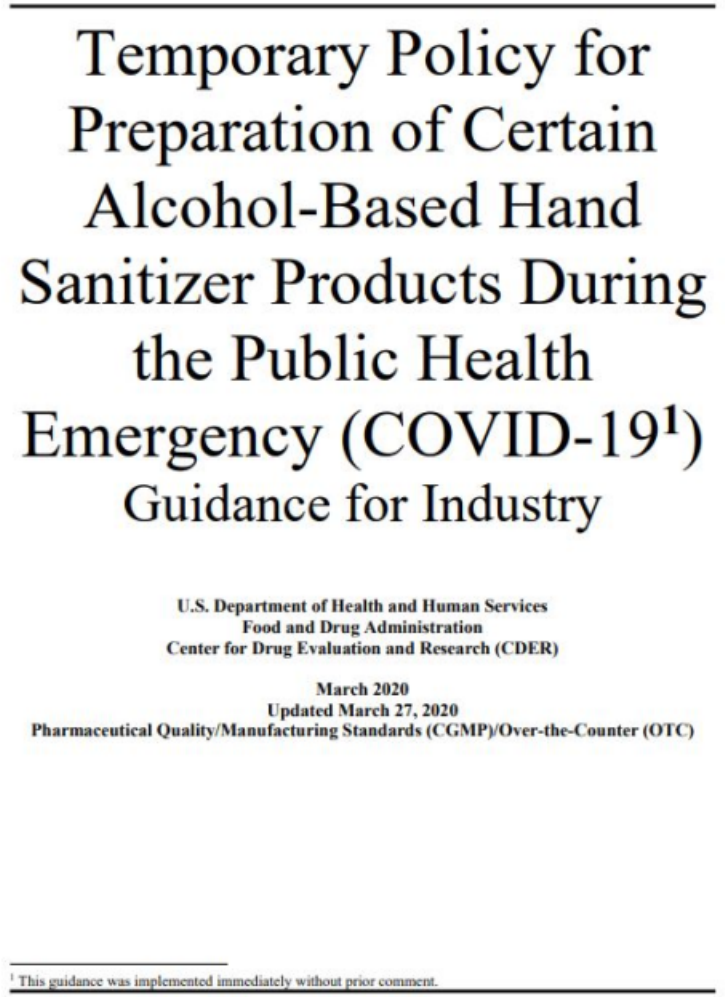
LATEST FDA POSITION:

The FDA will be relaxing its current policies to provide more flexibility on:

- **approved denaturing formulas**,
- the proof of the alcohol (ethanol **OR** isopropyl alcohol) being used in the hand sanitizer,
- the grade of alcohol, and
- the grade of hydrogen peroxide.

FDA EMERGENCY GUIDELINES

- The FDA has issued emergency guidance to address the Coronavirus Disease 2019 (COVID-19) public health emergency. The guidance was being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate.
- FDA's guidance is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.
- FDA issued this guidance to communicate its policy for the temporary manufacture of ethanol products by firms that manufacture alcohol for incorporation into alcohol-based hand sanitizer products under the circumstances described in this guidance (alcohol production firms) for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.
- **At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance.**



Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19[1])

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2020
Updated March 27, 2020
Pharmaceutical Quality/Manufacturing Standards (CGMP)/Over-the-Counter (OTC)

[1] This guidance was implemented immediately without prior comment.

FDA EMERGENCY FORMULATION

- Because of the public health emergency posed by COVID-19, FDA does not intend to take action against alcohol production firms that manufacture alcohol (*i.e.*, ethanol or ethyl alcohol) for use as the Active Pharmaceutical Ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency declared by the Secretary of HHS on January 31, 2020, **provided the following EIGHT circumstances are present**:

FDA EMERGENCY FORMULATION

1. The hand sanitizer is **manufactured using only the following ingredients** in the preparation of the product:

a. Select one of two options-

(1) Alcohol (ethanol) that is not less than 94.9% ethanol by volume; NOTE: lower ethanol content alcohol falls within this policy so long as it is labeled accordingly and the finished hand sanitizer meets the ethanol volume to content concentration of 80%. OR

(2) Isopropyl Alcohol;

b. Glycerin (glycerol) United States Pharmacopeia (USP) or Food Chemical Codex (also known as "food grade");

c. Hydrogen peroxide;

d. Sterile water, *e.g.,* by boiling, distillation, or other process that results in water that meets the specifications for Purified Water USP. Water should be used as quickly as possible after it is rendered sterile or purified.

2. The **alcohol (ethanol) is denatured** either by the alcohol producer or at the point of production of the finished hand sanitizer product. TTB regulations in 27 CFR part 20 and 21 provide a number of formulas for denaturing alcohol.

Formulas for use in hand sanitizers include:

a. Formula 40A or 40B with or without the tert-butyl alcohol

b. Formula 3C (isopropyl alcohol)

FDA EMERGENCY FORMULATION

3. The hand sanitizer is **manufactured according to the following formula consistent with World Health Organization (WHO) recommendations**:

a. **Alcohol (ethanol)** (80%, volume/volume (v/v)) in an aqueous solution; or Isopropyl Alcohol (75%, v/v) in an aqueous solution.

b. **Glycerin (glycerol)** (1.45% v/v).

c. **Hydrogen peroxide** (0.125% v/v).

d. **Sterile distilled water or boiled cold water**. The firm does not add other active or inactive ingredients, such as ingredients to improve the smell or taste, due to the risk of accidental ingestion in children. Different or additional ingredients may impact the quality and potency of the product.

Beyond denatured alcohol, water, and denaturants (if added at the point of production), the alcohol production firm does not add other ingredients. Different or additional ingredients in the API may impact the quality and potency of the finished hand sanitizer product, and may increase the risk of accidental ingestion in children.

FDA EMERGENCY GUIDELINES

4. The manufacturer pays particular attention to ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product. If the alcohol is to be distributed to another firm for producing the hand sanitizer, it is labeled with the ethanol content determined by an appropriate test so that the hand sanitizer can be reliably produced at the intended labeled strength.

5. The alcohol is prepared under sanitary conditions and equipment used is well maintained and fit for this purpose.

6. The alcohol production firm uses the most accurate method of analysis available at the site for verification of ethanol content in a sample before each batch is released for distribution or for use in producing the hand sanitizer. Methods can include gas chromatography (GC), specific gravity (*e.g.*, alcoholmeter, hydrometer, pycnometer, or gravity density meter), or another test that is at least as accurate. The sample tested can be from the final API before packaging (if distributed as an API) or before actual use in producing the hand sanitizer.

FDA EMERGENCY GUIDELINES

7. The alcohol API, if distributed to other producers, is labeled consistent with the attached labeling in the FDA's Guidance **Appendix A** (Labeling for Ethyl Alcohol Formulation Consumer Use), **Appendix B** (Labeling for Isopropyl Alcohol Formulation Consumer Use), **Appendix C** (Labeling for Ethyl Alcohol Formulation Health Care Personnel Hand-rub Use), or **Appendix D** (Labeling for Isopropyl Alcohol Formulation Health Care Personnel Hand-rub Use). **Appendices are reproduced in the following slides**. Additionally, each label should include the name and contact information of the manufacturer.

8. Alcohol production firms register their facility and list these products in the FDA Drug Registration and Listing System (DRLS, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/drug-registration-and-listing-system-drls-and-edrls). Upon completion of registration and listing, firms receive automatic confirmation from FDA and do not need to wait for further communication from FDA before they begin to manufacture and distribute these products. FDA relies on registration and listing information to help manage drug shortages, monitor safety issues that may arise with product distributed to the public, and manage product recalls, among other important FDA public safety activities. FDA's help desk is standing by to assist with facilitating this process and can be contacted by sending an email to: edrls@fda.hhs.gov.

If alcohol production firms receive adverse event reports, they are encouraged to submit them to FDA's MedWatch Adverse Event Reporting program:

- **Complete and submit the report online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm ; or**
- **Download and complete the form, then submit it via fax at 1-800-FDA-0178**

FDA LABELING GUIDELINES

Appendix A. Labeling for Ethyl Alcohol Formulation Consumer Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] — ***Purpose***
Alcohol 80% v/v ..... Antiseptic

Use[s]
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Appendix B. Labeling for Isopropyl Alcohol Formulation Consumer Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s] — ***Purpose***
Isopropyl alcohol 75% v/v ..... Antiseptic

Use[s]
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

FDA LABELING GUIDELINES

Appendix C. Labeling for Ethyl Alcohol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s]	***Purpose***
Alcohol 80% v/v	Antiseptic

Use[s]
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Appendix D. Labeling for Isopropyl Alcohol Formulation Health Care Personnel Handrub Use

PRINCIPAL DISPLAY PANEL (FRONT OF PACKAGE):

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s]	***Purpose***
Isopropyl alcohol 75% v/v	Antiseptic

Use[s]
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings
For external use only. Flammable. Keep away from heat or flame

Do not use
- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

WHO-APPROVED PRODUCTION FORMULAS

The World Health Organization (WHO) has determined that alcohol-based hand-rubs are the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands.

A scalable version of WHO Formula #1 is as follows:

HAND SANITIZER (WHO FORMULA)

HSHCV001-0002

		Production Batch Values							
Name	**Code**	**liters**	**kg**	**1 liter values (mL)**	**% Vol**	**%ABV**	**LPA**	**g/mL**	**%TotAlc**
ETHANOL 96% ABV	GNS	4,166.67	3,364.58	833.33	83.333	96.0	4000.0	0.80	
WATER, DEMINERALIZED	WD	552.33	551.34	110.47	11.047	0.0	0.0	0.99	
GLYCERINE, 98%	GLY	72.50	91.35	14.50	1.450	0.0	0.0	1.26	
HYDROGEN PEROXIDE 3%	H2O2	208.50	231.44	41.70	4.170	0.0	0.0	1.11	
	Total	**5,000.00**	**4,238.71**	**1,000.00**	**100.0**		**4,000.0**		

Batch Size (liters)	**5,000.0**
Target %ABV	**80**

APPROVED PRODUCTION FORMULAS

o ***Alcohol Grade***: Ethanol used can be USP, FCC or technical grade, provided no additives would remain in the product. FDA has specified that alcohol (ethanol) used for this purpose must be derived from distillation or fermentation processes typically used for consumable goods. Alcohol derived from synthetic processes can be used only if it meets USP or FCC grade.

o ***Glycerin/Glycerol***: FDA clarified that these are the same chemical and that both USP and FCC grade glycerin is acceptable.

o ***Hydrogen peroxide***: Technical grade hydrogen peroxide falls within this policy if the concentration is within that of Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP. FDA requests that firms formulate to a final strength of 0.125% v/v hydrogen peroxide using Hydrogen Peroxide Concentrate USP or Hydrogen Peroxide Topical Solution USP (in the latter case provided the alcohol (ethanol or isopropyl alcohol) concentration remains within the specified level of 80% for ethyl alcohol or 75% for isopropyl alcohol).

• ***Denatured***: FDA requires the use of denatured alcohol and mandates the use of one of three TTB denaturing formulas: **40-A** and **40-B** (both of which can be used with or without the tert-butyl alcohol), and **3-C**, which contains isopropyl alcohol.

APPROVED PRODUCTION FORMULAS

- **40-A 27 CFR § 21.75 Formula No. 40-A *Formula.*** To every 100 gallons of alcohol add one pound of sucrose octaacetate and 1/8 gallon of *tert*-butyl alcohol.
- **40-B 27 CFR § 21.76 Formula No. 40-B *Formula.*** To every 100 gallons of alcohol add one-sixteenth avoirdupois ounce of denatonium benzoate, N.F., and 1/8 gallon of *tert*-butyl alcohol.
- **3-C, 27 CFR § 21.37 Formula No. 3-C *Formula.*** To every 100 gallons of alcohol add five gallons of isopropyl alcohol.

FDA stated as recently as March 30, 2020, that other potential formulas, including the inclusion of acetone (TTB Formula **23-A**), **currently ARE NOT approved for denaturing**. Firms that wish to use different denaturants (bitterants) should contact FDA at COVID-19-hand-sanitizers@fda.hhs.gov.

MINIMUM PROOF & REGISTRATION

Minimum Proof:

FDA requests that the alcohol be not less than 94.9% ethanol by volume prior to denaturing, which is consistent with the USP and FCC grade requirements for purity.

Lower ethanol content alcohol IS ALLOWED within the FDA's COVID-19 policy so long as:

(i) it is labeled accordingly and

(ii) the finished hand sanitizer meets the ethanol volume to content concentration of 80%.

Registration and Listing Required:

FDA's guidance requires that companies register their facility and list these products in the FDA Drug Registration and Listing System (DRLS).

Information regarding how to register your facility and hand sanitizer product can be found in the guidance document.

WHO APPROVED PRODUCTION METHODS

WHO Recommended Preparation Methods

1. The alcohol for the chosen formulation is poured into the large bottle or tank up to the graduated mark.
2. H_2O_2 is added using the measuring cylinder.
3. Glycerol is added using a measuring cylinder. As the glycerol is very viscous and sticks to the walls of the measuring cylinder, it can be rinsed with some sterile distilled or cold boiled water to be added and then emptied into the bottle/tank.
4. The bottle/tank is then topped up to the corresponding mark of the volume (10-litre or 50-litre) to be prepared with the remainder of the distilled or cold, boiled water.
5. The lid or the screw cap is placed on the bottle/tank immediately after mixing to prevent evaporation.
6. The solution is mixed by gently shaking the recipient where appropriate (small quantities),or by using a wooden, plastic or metallic paddle. Electric mixers should not be used unless “EX” protected because of the danger of explosion.
7. After mixing, the solution is immediately divided into smaller containers (*e.g.* 1000, 500 or 100 ml plastic bottles). The bottles should be kept in quarantine for 72 hours. This allows time for any spores present in the alcohol or the new or re-used bottles to be eliminated by H_2O_2.

WHO APPROVED PRODUCTION METHODS

WHO Recommended Local Production Methods

- ***Volume of production, containers***
- **10-liter** preparations: glass or plastic bottles with screw-threaded stoppers can be used.
- **50-liter** preparations: large plastic (preferably polypropylene, translucent enough to see the liquid level) or stainless steel tanks with an 80 to100 liter capacity should be used to allow for mixing without overflowing.
- The tanks should be calibrated for the ethanol/isopropyl alcohol volumes and for the final volumes of either 10 or 50 liters. It is best to mark plastic tanks on the outside and stainless steel ones on the inside.

Quality control

- If concentrated alcohol is obtained from local production, verify the alcohol concentration and make the necessary adjustments in volume to obtain the final recommended concentration. An alcoholmeter can be used to control the alcohol concentration of the final use solution; H_2O_2 concentration can be measured by titrimetry (oxydo-reduction reaction by iodine in acidic conditions).
- A higher level quality control can be performed using gas chromatography and the titrimetric method to control the alcohol and the hydrogen peroxide content, respectively. Moreover, the absence of microbial contamination (including spores) can be checked by filtration.
- For more detailed guidance on production and quality control of both formulations, see the "WHO-recommended hand antisepsis formulation - guide to local production" (Implementation Toolkit available at http://www.who.int/gpsc/en/).

OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

- A **Material Safety Data Sheet (MSDS)** is a safety document required by the Occupational Safety and Health Administration (OSHA) that contains data about the physical properties of a particular hazardous substance.
- MSDS sheets are created for a variety of hazard materials including compressed gases, flammable and combustible liquids, oxidizing materials, poisonous or infectious material, corrosive material and dangerously reactive materials. Sanitizer falls within this classification.
- The purpose of the Material Safety Data Sheet information is to convey chemical safety and hazard information to the end user (employees exposed to hazardous chemicals, employees who store dangerous chemicals, and emergency responders such as: firefighters, hazardous material crews, and emergency medical technicians).
- Material Data Safety Sheets are a critical component of the United States OSHA Hazard Communication Standard, which states that “anyone who might handle, work with or be exposed to hazardous materials must have access to the Material Safety Data Sheets.”

OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

An MSDS sheet is a safety document with at least nine-sections detailing the toxicity, use, storage, handling and emergency procedures of hazardous substances. The OSHA requirements for MSDS format include placing the following categories on every Material Safety Data Sheet:

- Section I. Manufacturer's Name and Contact Information;
- Section II. Hazardous Ingredients/Identity Information;
- Section III. Physical/Chemical Characteristics;
- Section IV. Fire and Explosion Hazard Data;
- Section V. Reactivity Data;
- Section VI. Health Hazard Data;
- Section VII. Precautions for Safe Handling and Use; and
- Section VIII. Control Measures.

OSHA-MANDATED PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

From OSHA Site

Be careful about your SDS Sheets as the penalties are set by OSHA as listed below:

OSHA Penalties

Below are the penalty amounts adjusted for inflation as of Jan. 2, 2018.

Type of Violation	Penalty
Serious Other-Than-Serious Posting Requirements	$12,934 per violation
Failure to Abate	$12,934 per day beyond the abatement date
Willful or Repeated	$129,336 per violation

PRODUCTION SAFETY

MSDS Safety Data Sheet for Hand Sanitizer

Both chemical manufacturers and employers with chemicals in the workplace must comply with GHS MSDS regulation.

Distillers making sanitizer also must comply.

OSHA violations (failure to comply with OSHA requirements) may result in OSHA citations and OSHA penalties upwards of $70,000 per violation per instance.

SAFETY DATA SHEET

GOJO

PURELL® VF481™ Hand Sanitizer Gel

Version 1.1 | SDS Number: 400000000475 | Revision Date: 01/29/2018

SECTION 1. IDENTIFICATION

Product name	:	PURELL® VF481™ Hand Sanitizer Gel

Manufacturer or supplier's details

Company name of supplier	:	GOJO Industries, Inc.
Address	:	One GOJO Plaza, Suite 500 Akron, Ohio 44311
Telephone	:	1 (330) 255-6000
Emergency telephone number	:	CHEMTREC 1-800-424-9300 CHEMTREC +1-703-527-3887: Outside USA & CANADA

Recommended use of the chemical and restrictions on use

Recommended use	:	Hand Sanitizer
Restrictions on use	:	This is a personal care or cosmetic product that is safe for consumers and other users under normal and reasonably foreseeable use. Cosmetics and consumer products, specifically defined by regulations around the world, are exempt from the requirement of an SDS for the consumer. While this material is not considered hazardous, this SDS contains valuable information critical to the safe handling and proper use of the product for industrial workplace conditions as well as unusual and unintended exposures such as large spills. This SDS should be retained and available for employees and other users of this product. For specific intended-use guidance, please refer to the information provided on the package or instruction sheet.

PRODUCTION SAFETY

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3

Eye irritation : Category 2A

GHS label elements

Hazard pictograms :

Signal word : Warning

SAFETY DATA SHEET

PURELL® VF481™ Hand Sanitizer Gel

Version 1.1 SDS Number: 400000000475 Revision Date: 01/29/2018

Hazard statements : H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear eye protection/ face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.
Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Chemical name	CAS-No.	Concentration (%)
Ethyl Alcohol	64-17-5	>= 50 - < 70
Isopropyl Alcohol	67-63-0	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
If symptoms persist, call a physician.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if irritation develops and persists.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.

SAFETY DATA SHEET

PURELL® VF481™ Hand Sanitizer Gel

Version 1.1 SDS Number: 400000000475 Revision Date: 01/29/2018

Seek medical advice.

If swallowed : If swallowed, DO NOT induce vomiting.
Rinse mouth with water.
Obtain medical attention.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection and use the recommended protective clothing

PRODUCTION SAFETY

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Do not use a solid water stream as it may scatter and spread fire. Cool closed containers exposed to fire with water spray. Flash back possible over considerable distance. May form explosive mixtures in air. Exposure to decomposition products may be a hazard to health. Carbon oxides
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers.
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Material can create slippery conditions.

3 / 13

SAFETY DATA SHEET

GOJO®

PURELL® VF481™ Hand Sanitizer Gel

Version 1.1 SDS Number: 400000000475 Revision Date: 01/29/2018

Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. Keep in suitable, closed containers for disposal. Clean contaminated floors and objects thoroughly while observing environmental regulations.

PRODUCTION SAFETY

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : For personal protection see section 8.
Keep away from heat and flame.
Use with local exhaust ventilation.
Avoid contact with eyes.

Conditions for safe storage : Take measures to prevent the build up of electrostatic charge.
Keep in properly labelled containers.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Store in accordance with the particular national regulations.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethyl Alcohol	64-17-5	TWA	1,000 ppm 1,900 mg/m3	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m3	OSHA Z-1
		STEL	1,000 ppm	ACGIH
Isopropyl Alcohol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		TWA	400 ppm 980 mg/m3	NIOSH REL
		ST	500 ppm 1,225 mg/m3	NIOSH REL
		TWA	400 ppm 980 mg/m3	OSHA Z-1

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Isopropyl Alcohol	67-63-0	Acetone	Urine	End of	40 mg/l	ACGIH

PURELL® VF481™ Hand Sanitizer Gel

				shift at end of workweek		BEI

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : No special protective equipment required.

Eye protection : Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : No special measures necessary provided product is used correctly.

Protective measures : Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place.
Ensure that eye flushing systems and safety showers are located close to the working place.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with eyes.

PRODUCTION SAFETY

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	clear, greenish-blue
Odour	:	alcohol-like
Odour Threshold	:	No data available
pH	:	3.8 - 5.2, (20 °C)
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	75.00 °C
Flash point	:	26.50 °C
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	0.8742 g/cm3
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Thermal decomposition	:	The substance or mixture is not classified self-reactive.
Viscosity		
Viscosity, kinematic	:	80 - 600 mm2/s (20 °C)
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

PRODUCTION SAFETY

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Vapours may form explosive mixture with air.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation

Eye contact

Skin contact

Acute toxicity

Not classified based on available information.

Components:

Ethyl Alcohol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Isopropyl Alcohol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 72.6 mg/l
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Ethyl Alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Isopropyl Alcohol:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Ethyl Alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Isopropyl Alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.
Respiratory sensitisation: Not classified based on available information.

Components:

Ethyl Alcohol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Isopropyl Alcohol:
Test Type: Buehler Test
Exposure routes: Skin contact

Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Ethyl Alcohol:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Test species: Mouse
Application Route: Ingestion
Result: negative

Isopropyl Alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Test species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Isopropyl Alcohol:
Species: Rat
Application Route: inhalation (vapour)
Exposure time: 104 weeks
Method: OECD Test Guideline 451
Result: negative

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Ethyl Alcohol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Isopropyl Alcohol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

Components:
Isopropyl Alcohol:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:
Ethyl Alcohol:
Species: Rat
NOAEL: 2,400 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Isopropyl Alcohol:
Species: Rat
NOAEL: 5000 ppm
Application Route: inhalation (vapour)
Exposure time: 104 w
Method: OECD Test Guideline 413

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Ethyl Alcohol:
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

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Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to algae : EC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 9.6 mg/l
Exposure time: 9 d

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 32.1 mg/l
Exposure time: 0.25 h

Isopropyl Alcohol:
Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

Toxicity to bacteria : EC50 (Pseudomonas putida): > 1,050 mg/l
Exposure time: 16 h

Persistence and degradability

Components:
Ethyl Alcohol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Isopropyl Alcohol:
Biodegradability : Result: rapidly degradable

Bioaccumulative potential

Components:
Ethyl Alcohol:
Partition coefficient: n-octanol/water : log Pow: -0.35

Isopropyl Alcohol:
Partition coefficient: n-octanol/water : log Pow: 0.05

Mobility in soil
No data available

Other adverse effects
No data available

Product:

Version 1.1 SDS Number: 400000000475 Revision Date: 01/29/2018

Regulation : 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks : This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR
UN/ID No. : UN 1987
Proper shipping name : Alcohols, n.o.s.
(Ethanol, Propan-2-ol)
Class : 3
Packing group : III
Packing instruction (cargo aircraft) : 366
Packing instruction (passenger aircraft) : 355

IMDG-Code
UN number : UN 1987
Proper shipping name : ALCOHOLS, N.O.S.
(Ethanol, Propan-2-ol)
Class : 3
Packing group : III
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : no

National Regulations

49 CFR
UN/ID/NA number : UN 1987
Proper shipping name : Alcohols, n.o.s.
Class : 3
Packing group : III
ERG Code : 127
Marine pollutant : no

DISTILLED SPIRITS COUNCIL OF THE UNITED STATES

PRODUCTION SAFETY

GRAY ROBINSON RELATIONSHIPS | RESOURCES | RESULTS

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 311/312 Hazards : Fire Hazard
Acute Health Hazard

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Isopropyl Alcohol	67-63-0	3.4086 %

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

Ethyl Alcohol	64-17-5	65.2821 %
Isopropyl Alcohol	67-63-0	3.4086 %

This product does not contain any VOC exemptions listed under the U.S. Clean Air Act Section 450.

Clean Water Act

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

Ethyl Alcohol	64-17-5	50 - 70 %
Isopropyl Alcohol	67-63-0	1 - 5 %

Pennsylvania Right To Know

Ethyl Alcohol	64-17-5	50 - 70 %
Water (Aqua)	7732-18-5	30 - 50 %
Isopropyl Alcohol	67-63-0	1 - 5 %

New Jersey Right To Know

Ethyl Alcohol	64-17-5	50 - 70 %
Water (Aqua)	7732-18-5	30 - 50 %
Isopropyl Alcohol	67-63-0	1 - 5 %

California Prop 65 This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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The components of this product are reported in the following inventories:

TSCA	:	On TSCA Inventory
AICS	:	On the inventory, or in compliance with the inventory
DSL	:	On the inventory, or in compliance with the inventory
ENCS	:	On the inventory, or in compliance with the inventory
ISHL	:	On the inventory, or in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TCSI (Taiwan), TSCA (USA)

SECTION 16. OTHER INFORMATION

Further information

NFPA:

HMIS III:

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 01/29/2018

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Storage, Distribution, Marketing and Public Relations

Storage:

1. Product may be stored away from the licensed premises if space is a concern;

Getting your produced sanitizer into the right hands (delivery logistics):

- Product may be transported in bulk for easier distribution away from the place of manufacture, and packaging in consumer friendly package sizes is not necessary at that point in the process;
- Detailed record keeping is recommended.

Getting the word out about your good efforts

CONCLUSION: *What Remains to be Done*:

Be prepared if you are audited two years later – Best practices for record-keeping.

Support Other Industry Members – especially retailers and their employees:

- US Bartender Guild – COVID-19 State-by-State: State-by-state resources for workers during the COVID-19 crisis.
- Another Round, Another Rally Fund: We're offering $500 relief grants for hospitality workers who lost their jobs or had their hours slashed in the wake of the COVID-19 outbreak. We're also collecting donations from community members willing to help their hospitality-industry friends and neighbors stay afloat in this time of uncertainty. To apply for a grant or make a donation, use the links below.
- Lift Your Spirits Fund: Make a video in which you mix your favorite drink, say a toast to those affected in the restaurant, foodservice and hospitality industry, and post it to your social media accounts using ***#LiftYourSpirits***. The last step is to challenge your friends to do the same and to send a gift to the National Restaurant Association Educational Foundation (NRAEF) that turns a tip into a donation for restaurant, foodservice and hospitality workers impacted by the COVID-19 crisis!
- USBG Emergency Fund: Bartender emergency assistance program available to all bartenders or the spouse or child of a bartender.
- RWCF Crisis Relief Fund: A crisis relief fund to direct money to organizations leading on-the-ground efforts in the restaurant community, to provide zero-interest loans to businesses to maintain payroll during closure or re-open once this crisis has passed, and to establish a relief fund for individual workers facing economic hardships or health crises as a direct result of COVID-19.
- OFW Emergency Fund: Providing free, cash assistance to restaurant workers, delivery drivers and other tipped workers and service workers — who are seeing their income decline during this disaster, or aren't able to work because of quarantines or other health concerns.
- CORE Gives: CORE grants support to children of food and beverage service employees navigating life-altering circumstances.
- Rent Assistance: RentAssistance provides a directory of rental assistance agencies and organizations that will help you pay your rent. Some listings are government organizations other are non-profits and charities that offer rental assistance programs.
- Dining Bonds Initiative: A Dining Bond works like a savings bond, where you can purchase a "bond" at a value rate to be redeemed for face value at a future date.
- Go Tip 'Em!: Pick a bartender, and send them a tip for the drink not served.